Can electrically-assisted bicycles be recommended for patients with heart disease?

Submission date	Recruitment status No longer recruiting	Prospectively registered		
16/06/2015		Protocol		
Registration date	Overall study status	Statistical analysis plan		
08/07/2015	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
22/01/2019	Circulatory System			

Plain English summary of protocol

Background and study aims

Cardiac rehabilitation is proven to be effective in coronary artery disease patients and is recommended by the European Society of Cardiology. However the long-term benefits are often poor, because patients do not adopt healthy lifestyle behaviours (including regular exercise training). To overcome this problem, alternative rehabilitation methods have been assessed. Especially for the elderly, electrically-assisted cycling could be a valuable alternative to classical cycling. There is little evidence about this approach and the aim of this observational study is to find out more.

Who can participate?

Adult patients diagnosed with coronary artery disease.

What does the study involve?

Participants perform the same route three times in Hasselt, Belgium. The first time they use a classical bicycle, the second and/or third time an electrically-assisted bicycle. During each cycling period, a number of measurements are taken.

What are the possible benefits and risks of participating?

A risk is that participants could experience exercise-related complications during the cycling period. However, participants are supervised by at least one person who can intervene whenever necessary.

Where is the study run from? Jessa Hospital, Hasselt (Belgium)

When is the study starting and how long is it expected to run for? November 2014 to April 2015

Who is funding the study? Heart Center Hasselt (Belgium)

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Comparing the metabolic load of electrically-assisted cycling with classical cycling in coronary artery disease patients after phase II of cardiac rehabilitation.

Study objectives

The metabolic load of electrically-assisted cycling is significantly different, compared to classical cycling in coronary artery disease patients after phase II of cardiac rehabilitation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Jessa Hospital Ethics Committee, 07/112014, ref 14.73/reva14.10.

Study design

Single-centre prospective observational trial

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patients with coronary artery disease, treated with percutaneous coronary intervention or coronary artery bypass grafting.

Interventions

Every patient was requested to perform a cycling route (of 10 km) in Hasselt (Belgium). Patients performed the cycling route 3 times.

The first time, a classical bicycle was used. The second and/or third time electrically assisted bicycles were used (light and heavy assistance).

Intervention Type

Other

Primary outcome(s)

VO2, assessed by ergospirometry (Oxycon mobile device) during whole cycling sessions.

VO2 was recorded during all cycling sessions.

Key secondary outcome(s))

- 1. VCO2, assessed by ergospirometry (Oxycon mobile device) during whole cycling sessions
- 2. RER, assessed by ergospirometry (Oxycon mobile device) during whole cycling sessions
- 3. VE, assessed by ergospirometry (Oxycon mobile device) during whole cycling sessions
- 4. Time of cycling sessions, recorded by stopwatch
- 5. Perceived exertion, assessed twice at predefined parcours locations with Borg scale Kcal, deduced from VO2 and total time of cycling sessions

VCO2, RER, VE, perceived exertion (Borg scale) were recorded during all cycling sessions.

VO2 or oxygen consumption - VO2 is defined as the volume of O2 extracted from inspired air in a given period of time.

VCO2 or carbon dioxide output - VCO2 is defined as the amount of CO2 exhaled from the body per unit of time.

RER or respiratory exchange ratio - RER is defined as: RER= VCO2/VO2. The RER is determined by the fuels used for metabolism. RER is 1 for carbohydrates; RER is 0,7 for lipids and RER is 0,85 for carbohydrates and lipids.

VE or minute ventilation - VE is the volume of expired air exhaled from the lungs in 1 minute.

Completion date

01/05/2015

Eligibility

Key inclusion criteria

- 1. Coronary artery disease patients, treated with percutaneous coronary intervention or coronary artery bypass grafting
- 2. Patients should have completed phase II of cardiac rehabilitation
- 3. Absence of severe pulmonary and/or renal disease

- 4. Absence of neurological and/or orthopedic disease (that would limit the patient's possibility to cycle)
- 5. Absence of pacemaker
- 6. Gender: both male and female
- 7. Age: between 50-75 years old
- 8. Signed informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

Key exclusion criteria

- 1. Presence of severe pulmonary and/or renal disease
- 2. Presence of neurological and/or orthopedic disease (that would limit the patient's possibility to cycle)
- 3. Presence of pacemaker
- 4. Age: <50 or > 75 years old

Date of first enrolment

10/11/2014

Date of final enrolment

01/04/2015

Locations

Countries of recruitment

Belgium

Study participating centre Jessa Hospital

Stadsomvaart 11 3500 Hasselt Hasselt Belgium 3500

Sponsor information

Organisation

Heart Center Hasselt

ROR

https://ror.org/03tw90478

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Heart Center Hasselt (Belgium)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018	22/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes